# **Regulatory Analysis**

Notice of Intended Action to be published: 641—Chapter 136

"Trauma Registry"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 147A.27

State or federal law(s) implemented by the rulemaking: Iowa Code section 147A.26

### Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 6, 2024 Microsoft Teams

10 a.m. Meeting ID: 268 876 122 100

Passcode: QXqezE

#### Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m.

on the date of the public hearing. Comments should be directed to:

Victoria L. Daniels

321 East 12th Street

Des Moines, Iowa 50319

Phone: 515.829.6021

Email: compliancerules@hhs.iowa.gov

# Purpose and Summary

High-quality data from the trauma registry are critical to inform quality improvement and measure the performance of the statewide trauma system. Proposed Chapter 136 provides

guidance to hospitals on high-quality data reporting of injured patients, which allows enhanced epidemiologic analysis to improve outcomes of injured patients in Iowa. This allows for focused quality improvement activities and maximizes the value of trauma benchmarking with the goal of reduced morbidity and mortality from injuries.

# Analysis of Impact

- 1. Persons affected by the proposed rulemaking:
- Classes of persons that will bear the costs of the proposed rulemaking:

There are no costs associated with this rulemaking.

• Classes of persons that will benefit from the proposed rulemaking:

The public, in general, benefits. The data collected helps inform trauma care throughout the state.

- 2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:
  - Quantitative description of impact:

All 118 hospitals in Iowa submit reports to the register. In 2022, 26,602 incidents were reported.

• Qualitative description of impact:

Without quality injury data from hospitals, there would not be a method for analysis of opportunities for improvement within the state trauma system, data-driven decision making, and the reduction of morbidity and mortality from injury. This includes local injury trends, severity of injury, hospital resources, and appropriate and timely care of the injured.

- 3. Costs to the State:
- Implementation and enforcement costs borne by the agency or any other agency:

Personnel and other administrative costs are borne by the agency.

• Anticipated effect on state revenues:

There is no anticipated effect on state revenues.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

Rulemaking is required under Iowa Code section 147A.27.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

None were considered because rules are required by law.

- 6. Alternative methods considered by the agency:
- Description of any alternative methods that were seriously considered by the agency:

None were considered because rules are required by law.

• Reasons why alternative methods were rejected in favor of the proposed rulemaking: Not applicable.

#### Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.

- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
  - Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

There is no impact on small business.

Text of Proposed Rulemaking

ITEM 1. Adopt the following **new** 641—Chapter 136:

#### CHAPTER 136

#### TRAUMA REGISTRY

**641—136.1(147A) Definitions.** For the purposes of these rules, the following definitions apply:

"Health care providers" for the purpose of this chapter includes licensed physicians, advanced registered nurse practitioners, physician assistants, and registered nurses.

"Inclusion criteria" means criteria determined by the department of health and human services and adopted by reference to determine which trauma patients are to be included in the trauma registry.

"Reportable patient data" means data and definitions determined by the department and adopted by reference to be reported to the trauma registry on trauma patients meeting the inclusion criteria.

"Trauma care facility" means the same as defined in Iowa Code section 147A.21.

"Trauma patient" means a victim of an external cause of injury that results in major or minor tissue damage or destruction caused by intentional or unintentional exposure to thermal, mechanical, electrical or chemical energy, or by the absence of heat or oxygen.

"Trauma registry" means the data repository operated by the department to collect and analyze reportable patient data on the incidence, severity, and causes of trauma, and that serves as the central registry for brain and spinal cord injuries described in rule 641—21.1(135) and farm-related injuries.

"Trauma survey team" means a group of health care providers contracted by the department to assist in verifying trauma care facilities' compliance with trauma criteria adopted by reference in 641—subrule 134.2(3).

# 641—136.2(147A) Trauma registry.

136.2(1) Trauma care facilities shall submit reportable patient data electronically to the department. Data shall be submitted in the trauma registry format operated by the department. The department may require those requesting the data to pay any or all of the reasonable costs associated with furnishing the reportable patient data.

**136.2(2)** Quality assurance of reported data.

- a. For the purpose of ensuring the completeness and quality of reportable patient data, the department or its designated trauma survey team may examine medical records to validate the accuracy of data submitted by a trauma care facility.
- b. Review of medical records by the department or its designated trauma survey team may be scheduled in advance with the trauma care facility.

**641—136.3(147A) Offenses and penalties.** All complaints, offenses and penalties will be addressed pursuant to rule 641—134.3(147A).

These rules are intended to implement Iowa Code section <u>147A.26</u>.